#14 Appeal Brief

DOCKET NO.: 4859-0029-0

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :

Koichi SUGITA et al. : GROUP ART UNIT: 1638

SERIAL NO: 09/477,730 : EXAMINER: COLLINS, C.

FILED: JANUARY 5, 2000 :

FOR: NOVEL VECTOR FOR INTRODUCING A GENE INTO A PLANT USING A SELECTABLE MARKER

APPEAL BRIEF

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

This is an appeal from the Final Rejection of the claims dated November 4, 2002.

I. REAL PARTY IN INTEREST

The real party in interest is Nippon Paper Industries Co., LTD., by assignment recorded March 2, 2000 at Reel/Frame 010684/0615.

II. RELATED APPEALS AND INTERFERENCES

Appellants, Appellants' legal representative and their assignee are not aware of any appeals or interferences which will directly affect or be directly affected by or having a bearing on the Board's decision in this appeal.

III. STATUS OF THE CLAIMS

The appealed claims are Claims 1-13, the only claims in the case.

IV. STATUS OF AMENDMENTS FILED UNDER 37 C.F.R. §1.116

No amendments have been filed subsequent to the Final Rejection dated November 4, 2002.

V. THE APPEALED CLAIMS

A copy of the appealed claims is submitted in the attached Appendix.

VI. SUMMARY OF THE INVENTION

The present invention relates to a vector for introducing a gene into a plant, which comprises:

a desired gene, wherein the desired gene is not a selectable marker gene, and

a plant hormone signal transduction gene as a selectable marker gene.

See the present specification at page 7, last paragraph, and page 18, last paragraph.

The present invention also relates to a vector as described above, which further contains a removable DNA element, wherein the selectable marker gene is positioned such that it behaves integrally with the removable DNA element, and wherein the desired gene is positioned such that it does not behave integrally with the removable DNA element. See the present specification at page 13, first paragraph, and page 23, second paragraph.

The present invention also relates to a vector as described above, wherein the selectable marker gene is present within the removable DNA element. See the present specification at page 13, first paragraph.

The present invention also relates to a vector as described above, which further contains a plant hormone synthesis gene together with the plant hormone signal transduction gene as selectable marker genes. See the present specification at the paragraph bridging pages 24 and 25.

The present invention also relates to a vector as described above, wherein the plant hormone signal transduction gene is a cytokinin signal transduction gene. See the present specification at page 22, last paragraph.

The present invention also relates to a vector as described above, wherein the cytokinin signal transduction gene is the *CKI1* gene derived from *Arabidopsis thaliana*. See the present specification at page 48, line 4-6.

The present invention also relates to a vector as described above, wherein the plant hormone synthesis gene is a cytokinin synthesis gene. See the present specification at paragraph bridging pages 11 and 12.

The present invention also relates to a vector as described above, wherein the cytokinin synthesis gene is the *ipt* (isopentenyl transferase) gene which is present on the T-DNA of *Agrobacterium tumefaciens*. See the present specification at page 12.

The present invention also relates to a vector as described above wherein the removable DNA element is derived from a site-specific recombination system. See the present specification at page 16, lines 3-5.

The present invention also relates to a vector as described above, wherein the desired gene encodes an enzyme. See the present specification at page 19, line 1.

The present invention also relates to a method of introducing a gene into a plant, comprising: introducing the vector as described above into a plant. See the present specification at the paragraph bridging pages 21 and 22.

The present invention also relates to a method of expressing a gene in plants, comprising: introducing the vector as described above into a plant, wherein the desired gene is expressed in the plant. See the present specification at the paragraph bridging pages 21 and 22.

The present invention also relates to a method of identifying plants which express a gene in a plant, comprising:

introducing the vector as described above into plants, and

identifying at least one plant which expresses the desired gene by selecting plants which express the plant hormone signal transduction gene.

See the present specification at the paragraph bridging pages 21 and 22.

VII. THE ISSUES OF THIS APPEAL

The issues of this appeal are:

(1) Whether the subject matter of Claims 1-5 and 7-13 fails to be described in such a way as to reasonably convey to one skilled in the art that the inventors had possession of the claimed invention at the time the present application was filed, as required by 35 U.S.C. §112, first paragraph. See pages 2 and 3 of the Final Rejection dated November 4, 2002.

(2) Whether Claims 1-5 are supported by an enabling disclosure, as required by 35 U.S.C. §112, first paragraph. See pages 3 and 4 of the Final Rejection dated November 4, 2002.

(3) Whether Claims 1-13 are obvious under 35 U.S.C. §103(a) over European Patent No. 0 716 147 (hereinafter referred to as "EP '147") or U.S. 5,965,791 (hereinafter referred to as "U.S. '791") in view of Kakimoto et al.

(Science, volume 274, pp. 982-985, November 8, 1996). See pages 4-6 of the Final Rejection dated November 4, 2002. Since EP '147 and U.S. '791 appear to be part of the same patent family, i.e, each reference contains the same disclosure, these rejections will be discussed together with reference to U.S. '791.

(4) Whether Claims 1-9 are unpatentable for obviousness-type double patenting over Claims 1, 2, 4, 5, 6, and 7 of U.S. '791 in view of Kakimoto et al.

VIII. GROUPING OF THE CLAIMS

The claims do not stand or fall together. The reasons for the claims not standing or falling together with the other claims will be pointed out and discussed below.

IX. ARGUMENTS IN TRAVERSAL OF THE REJECTIONS

Issue 1

At page 2 of the Official Action dated March 21, 2002, the Examiner states:

> The specification does not set forth what specific structural features define the claimed vectors comprising plant hormone signal transduction genes as selectable marker genes."

However, page 10 of the present specification provides a detailed description of plant hormone signal transduction genes which can be used as a selectable marker gene. In fact, several specific examples of such genes are provided. Just merely providing the names of these gene provides the required structural and functional description of these sequences because, as noted in the specification, these sequences are known in the literature. Thus,

Appellants did have possession of the claimed invention at the time the present application was filed.

Issue 2

Regarding enablement, the present specification provides a detailed description of how to make and use the claimed vector. As discussed above, the present specification provides a detailed description of plant hormone signal transduction genes at page 10, including several specific examples of such genes. The working Examples of the application at pages 27-45 provide specific details regarding how to make the claimed vector and select the tissue introduced the desired gene contained in the vector. Based on these teachings, one skilled in the art can readily prepare and use other vectors within the scope of the claims. The amount of experimentation would not be undue. Since the amount of experimentation necessary would not be undue, the claims are enabled.

The Examiner asserts at page 5, lines 7-12 in the Office Action that, since the "degradation" of endogenous chemical substances is well known to be essential to the maintenance of homeostasis in all biological systems, the existence of a "detoxification" mechanism against proteins that mediate plant hormone signal transduction would be essential.

However, the Examiner is confusing the "degradation" with the "detoxification". That is, the "degradation" means that a chemical substance is chemically changed to have a lower molecular weight, whereas the "detoxification" means that a chemical substance is chemically modified to thereby disappear its toxicity. Accordingly, the "degradation" does not always involve the "detoxification", and in the same manner, the "detoxification" does

not always involve the "degradation". Therefore, the above Examiner's assertion is incorrect in this point.

The plant hormone signal transduction gene used in the present invention expresses in plant cells and produces a protein which mediate the signal transduction of plant hormone. The protein produced mediates the signal transduction either directly or by "degradation". In this point, one of ordinary skill in the art can easily understand that the protein is not subjected to "detoxification" in plant cells. As discussed in the previous response filed on January 7, 2002, the protein functions in the signal transduction pathway of plants, is indispensable for growth and differentiation of all plants, and is naturally destined to exist in common to various plant cells.

Based on the foregoing, the claims satisfy the enablement requirement of 35 U.S.C. §112, first paragraph.

Issue 3

Claim 1

The present inventors have discovered that a plant hormone signal transduction gene can be used as the selectable marker gene in order to identify plants and plant tissue into which the desired gene is introduced. Using the plant hormone signal transduction gene as the selectable marker, the selection efficiency is dramatically improved.

The applied rejection is U.S. '791 in view of Kakimoto et al. Therefore, in order for the rejection to be sustainable, the combination of the teachings of U.S. '791 and Kakimoto et al. must suggest the claimed vector. For the reasons set forth below, that combination fails to do so.

U.S. '791 describes a vector containing a desired gene and a morphological abnormality induction (MAI) gene as a selectable marker (see the abstract). As recognized by the Examiner, this reference fails to teach a vector containing a plant hormone signal transduction gene (see the Official Action dated July 5, 2001, at page 9, numbered paragraph 41).

Kakimoto et al. describe a vector in which CKI1, a plant hormone signal transduction gene, is the desired gene and an antibiotic resistance gene was used as the selectable marker gene (see page 983). This is evident from Nos. 5 and 6 in the References and Notes at page 985 of the reference. As described therein, a cytokinin-independent mutant which was obtained by introducing the desired CKI1 gene was obtained was selected using the resistance to the antibiotic hygromycin as a selectable marker.

In the Official Action dated June 21, 2002, at page 7, the Examiner states:

> The Examiner maintains that Kakimoto et al. Teach a vector comprising a desired gene **and** a plant hormone signal transduction gene as a selectable marker gene. The desired gene of Kakimoto et al. is thus NOT a plant hormone signal transduction gene, but rather any of the additional genes of the Ti plasmid into which the plant hormone signal transduction gene was cloned. [Emphasis in original.]

This characterization of Kakimoto et al. is, simply put, incorrect.

One reading that reference would conclude that the purpose of the vector described therein was to express CKI1. Therefore, that gene was the desired gene. Therefore, since CKI1 is not a selectable marker gene, Kakimoto et al. fail to disclose a plant hormone signal transduction gene as a selectable marker gene.

One reading Kakimoto et al. would also conclude that the "additional genes of the Ti plasmid into which the plant hormone signal transduction gene was cloned" were present to assist and direct the expression of CKI1., not that they were desired genes to be expressed.

As discussed above, an antibiotic resistance gene was used as the selectable marker gene in the construct described by Kakimoto et al. Therefore, the reference fails to describe a vector comprising a plant hormone signal transduction gene as a selectable marker gene.

Thus, Kakimoto et al. fail to describe a vector containing (1) a desired gene which is not a plant hormone signal transduction gene and (2) a plant hormone signal transduction gene as a selectable marker gene.

U.S. '791 and Kakimoto et al., considered in combination, fail to suggest the claimed vector. The vectors described in these references fail to suggest a vector which contains a desired gene which is not a plant hormone signal transduction gene and a plant hormone signal transduction gene as a selectable marker gene. In Kakimoto et al. the desired gene is a plant hormone signal transduction gene, which is not a selectable marker gene. U.S. '791, as recognized by the Examiner, fails to teach a plant hormone signal transduction gene at all. The Examiner states at page 8 of the Official Action dated March 21, 2002, that the motivation comes from "the success of Kakimoto et al. In using a plant hormone signal transduction gene as a selectable marker gene in plants." However, as discussed above, a plant hormone signal transduction gene was not used as a selectable marker gene in Kakimoto et al. Rather, an antibiotic resistance gene was used as a selectable marker in that reference.

Based on the foregoing, U.S. '791 and Kakimoto et al., taken in combination, fail to suggest the claimed vector. Accordingly, the combined disclosures of these references fail to establish a prima facie case of obviousness.

Moreover, the experimental data set forth in the present specification is striking evidence of non-obviousness. The data demonstrate the unexpected effect that selection efficiency of gene-introduced tissue can be improved by selecting and using the plant

hormone signal transduction gene as the selectable marker gene as compared to the vector described in U.S. '791 (see page 22, the first full paragraph; paragraph bridging pages 32 and 33; page 35, the first full paragraph, *etc.* in the present specification). For example, in Examples 1 and 2, the *CKI1* gene is used as the selectable marker gene so that 100% desired gene (GUS gene)-introduced tissue is selected by using the morphology such as multiple buds as the index (see paragraph bridging pages 32 and 33; page 35, the first full paragraph in the present specification). On the other hand, in Comparative Examples 2 and 3 using only the *ipt* gene (plant hormone synthesis gene) as the selectable marker gene, the desired gene-introduced tissues are 14% and 0%, respectively, among the tissues selected using the morphology as the index (see pages 36 and 37 in the present specification). Therefore, the selection efficiency is much higher using the claimed vector as compared to the vector described in U.S. '791.

Based on the foregoing, Claim 1 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 2

Claim 2 depends from Claim 1 and further specifies a vector,

which further contains a removable DNA element,

wherein the selectable marker gene is positioned such that it behaves integrally with the removable DNA element, and wherein the desired gene is positioned such that it does not behave integrally with the removable DNA element.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a vector which additionally contains a removable DNA element, and where the selectable marker gene is positioned such

that it behaves integrally with the removable DNA element, and where the desired gene is positioned such that it does not behave integrally with the removable DNA element.

Based on the foregoing, Claim 2 is not obvious over the cited references.

Claim 3

Claim 3 depends from Claim 2 and further specifies that the selectable marker gene is present within the removable DNA element.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 2, as discussed above. These references certainly fail to suggest a vector in which the selectable marker gene is present within the removable DNA element.

Based on the foregoing, Claim 3 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 4

Claim 4 depends from Claim 1 and specifies that the vector further contains a plant hormone synthesis gene together with the plant hormone signal transduction gene as selectable marker genes.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a vector which additionally contains a plant hormone synthesis gene together with the plant hormone signal transduction gene as selectable marker genes.

Based on the foregoing, Claim 4 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 5

Claim 5 depends from Claim 1 and specifies that the plant hormone signal transduction gene is a cytokinin signal transduction gene.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest such vector which has the additional feature that the plant hormone signal transduction gene is a cytokinin signal transduction gene.

Based on the foregoing, Claim 5 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 6

Claim 6 depends from Claim 5 and specifies that the cytokinin signal transduction gene is the *CKI1* gene derived from *Arabidopsis thaliana*.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 5, as discussed above. These references certainly fail to suggest a such vector which has the additional feature that the cytokinin signal transduction gene is the *CKI1* gene derived from *Arabidopsis thaliana*.

Accordingly, Claim 6 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 7

Claim 7 depends from Claim 4 and specifies that the plant hormone synthesis gene is a cytokinin synthesis gene.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 4, as discussed above. These references certainly fails to suggest such a vector having the additional feature that the plant hormone synthesis gene is a cytokinin synthesis gene.

Accordingly, Claim 7 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 8

Claim 8 depends from Claim 7 and further specifies that the cytokinin synthesis gene is the *ipt* (isopentenyl transferase) gene which is present on the T-DNA of *Agrobacterium tumefaciens*.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 7, as discussed above. These references certainly fail to suggest a vector having the additional feature that the cytokinin synthesis gene is the *ipt* (isopentenyl transferase) gene which is present on the T-DNA of *Agrobacterium tumefaciens*.

Based on the foregoing, Claim 7 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 9

Claim 9 depends from Claim 2 and further specifies that the removable DNA element is derived from a site-specific recombination system.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 2, as discussed above. These references certainly fail to suggest a vector having the additional feature that the removable DNA element is derived from a site-specific recombination system.

Based on the foregoing, Claim 9 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 10

Claim 10 depends from Claim 1 and further specifies that the desired gene encodes an enzyme.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a vector having the additional feature that the desired gene encodes an enzyme.

Based on the foregoing, Claim 10 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 11

Claim 11 is directed to a method of introducing a gene into a plant, comprising introducing the vector of Claim 1 into a plant.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a method of introducing a gene into a plant using that vector as claimed.

Accordingly, Claim 11 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 12

Claim 12 is directed to a method of expressing a gene in plants, comprising introducing the vector of Claim 1 into a plant, wherein the desired gene is expressed in the plant.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a method of expressing a gene in plants using that vector as claimed.

Based on the foregoing, Claim 12 is not obvious over U.S. '791 in view of Kakimoto et al.

Claim 13

Claim 13 is directed to a method of identifying plants which express a gene in a plant, comprising:

introducing the vector of Claim 1 into plants, and

identifying at least one plant which expresses the desired gene by selecting plants which express the plant hormone signal transduction gene.

U.S. '791 in view of Kakimoto et al. fail to suggest the vector of Claim 1, as discussed above. These references certainly fail to suggest a method of identifying plants which express a gene in a plant using that vector as claimed.

Accordingly, Claim 13 is not obvious over U.S. '791 in view of Kakimoto et al.

Issue 4

Claims 1-9 of the present application are not obvious over Claims 1, 2, and 4-7 of U.S. '791 in view of Kakimoto et al. for the same reasons that the pending claims are not obvious over the complete disclosure of U.S. '791 and Kakimoto et al., as discussed above with respect to Issue 3, the contents of which is incorporated herein by reference.

X. RELIEF REQUESTED

Appellants request a ***reversal*** of the Examiner's rejections of:

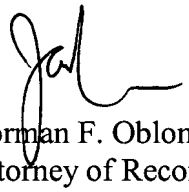
(1) Claims 1-5 and 7-13 under 35 U.S.C. §112, first paragraph,

(2) Claims 1-13 under 35 U.S.C. §103(a), and

(3) Claims 1-9 for obviousness-type double patenting over Claims 1, 2, and 4-7 of U.S. Patent No. 5,965,791 (U.S. '791) in view of Kakimoto et al. of the appealed claims under 35 U.S.C.

Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.



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APPENDIX

Claims 1-13 of U.S. application serial No. 09/477,730 are reproduced below:

1. A vector for introducing a gene into a plant, which comprises:

a desired gene, wherein the desired gene is not a selectable marker gene, and

a plant hormone signal transduction gene as a selectable marker gene.

2. The vector according to claim 1,

which further contains a removable DNA element,

wherein the selectable marker gene is positioned such that it behaves integrally with the removable DNA element, and wherein the desired gene is positioned such that it does not behave integrally with the removable DNA element.

3. The vector according to claim 2, wherein the selectable marker gene is present within the removable DNA element.

4. The vector according to claim 1, which further contains a plant hormone synthesis gene together with the plant hormone signal transduction gene as selectable marker genes.

5. The vector according to claim 1, wherein the plant hormone signal transduction gene is a cytokinin signal transduction gene.

6. The vector according to claim 5, wherein the cytokinin signal transduction gene is the *CKI1* gene derived from *Arabidopsis thaliana*.

7. The vector according to claim 4, wherein the plant hormone synthesis gene is a cytokinin synthesis gene.

8. The vector according to claim 7, wherein the cytokinin synthesis gene is the *ipt* (isopentenyl transferase) gene which is present on the T-DNA of *Agrobacterium tumefaciens*.

9. The vector according to claim 2, wherein the removable DNA element is derived from a site-specific recombination system.

10. The vector of Claim 1, wherein the desired gene encodes an enzyme.

11. A method of introducing a gene into a plant, comprising:

introducing the vector of Claim 1 into a plant.

12. A method of expressing a gene in plants, comprising:

introducing the vector of Claim 1 into a plant, wherein the desired gene is expressed in the plant.

13. A method of identifying plants which express a gene in a plant, comprising:

introducing the vector of Claim 1 into plants, and

identifying at least one plant which expresses the desired gene by selecting plants which express the plant hormone signal transduction gene.